FDA 510(k) Premarket Notification

K862349 EASY-TEST EMIT PHENYTOIN(PHTN) ITEM # 67535/93

CLEARED

Jul 7, 1986
17 days to decision

K862349 · Product code: **DIP** · Toxicology
Source: https://www.510kdatabase.net/k862349/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Jun 20, 1986
Decision date	Jul 7, 1986
Days to decision	17 days
Third-party review	No

APPLICANT

Company	**Em Diagnostic Systems, Inc.**
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k862349/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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